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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,295	10/28/2003	Joseph A. Gonzales	A-2966-AU	4188
7590 11/02/2005				
Richard L. Myers 22872 Avenida Empresa Rancho Santa Margarita, CA 92688				
			EXAMINER AHMED, AAMER S	
			ART UNIT 3763	PAPER NUMBER

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/695,295	GONZALES ET AL.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on 27 September 2005.

2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 11-25 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-10 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All    b) ☐ Some \*    c) ☐ None of:

        1. ☐ Certified copies of the priority documents have been received.

        2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Election/Restrictions*

Claims 11-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method of making and method of using claims, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 27<sup>th</sup>, 2005. Furthermore, Applicant's election with traverse of Species A, Figure 6 in the reply filed on September 27<sup>th</sup>, 2005 is acknowledged. Applicant timely traversed the restriction (election) requirement. Applicant's argument that Species "D", directed to Figure 13 and Species "B" directed to Figure 8 are of the same species is acknowledged and therefore the proper election requirement is as follows:

Species	Figure
A:	6
B:	8, 13
C:	10

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravener et al U.S. 5,360,417. Gravener et al ('417) discloses a surgical valve (12) having an axis extending between a proximal (16) and a distal end (10), comprising a housing (12) including a proximal (26) housing portion and a distal housing portion (18) cooperating with the proximal housing portion (26) to define a gel cavity (42), a seal material disposed in the gel cavity, the seal

material including a gel having non-compressible characteristics; a proximal guide tube (22) extending axially proximally from the proximal housing portion; the proximal guide tube facilitating insertion of a surgical instrument into the seal material, a distal guide tube (22) extending axially distally from the distal housing portion, the distal guide tube facilitating retrograde insertion of the surgical instrument (44) into the surgical seal (see figure 7); and wherein the proximal guide tube (22) includes exterior portions (22) extending proximally of the proximal housing portion (26); and interior portions (34) extending distally of the proximal housing portion (26); and wherein the seal material (42) defines an axial channel through the gel; and the proximal guide tube (22) contacts the seal material around the axial channel at the proximal end of the valve (see figure 7); and wherein the seal material and the first housing portion form a subassembly free of a circumferential seal between the seal material and the first housing portion; and subassembly to form a circumferential seal between the gel and the first housing portion the proximal guide tube applies a force to the seal material in the subassembly to form a circumferential seal between the gel and the first housing portion (see figure 7).

Furthermore, Gravener ('417) discloses, a node (32) and an axial channel cavity (see figure 7), the seal material being configured with the channel in an open state, a subassembly including the seal material disposed in the gel a second housing portion disposed in juxtaposition to the first housing portion and applying a force to the seal material in the subassembly, the force being of a magnitude sufficient to place the channel of the seal material in a closed state (see figure 9); and wherein the guide tube (22) contacts the node (32) of the seal material to apply the force to the seal material.

Moreover, Gravener et al ('417) teaches, a gel disposed (42) within the gel cavity and having properties including flowability and incompressibility, the gel having characteristics for creating a pressure on the instrument to form a seal with the instrument, and means for moving the second housing portion relative to the first housing portion to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve (col. 4 line 64).

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gravener et al ('417) in view of Mollenauer et al U.S. Patent Number 5,514,109. Gravener et al ('417) discloses the valve as described above in reference to claim 1. Gravener fails to explicitly describe a luer lock coupled to the distal housing portion. Mollenauer ('109) describes a similar surgical valve with a luer lock (242), see figure 11. It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the surgical valve of

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Gravener et al ('417) by incorporating a luer lock of the type taught by Mollenauer et al ('109) in order to attach the tubing to the housing.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 20030139756 A1 Brustad, John R.  
US 20030208104 A1 Carrillo, Oscar R. JR. et al.  
US 5104389 A Deem; Mark E. et al.  
US 5738664 A Erskine; Timothy J. et al.  
US 4960412 A Fink; E. David  
US 20050090713 A1 Gonzales, Joseph A. et al.  
US 5722958 A Gravener; Roy D. et al.  
US 5542931 A Gravener; Roy D. et al.  
US 5634911 A Hermann; George D. et al.  
US 20050203543 A1 Hilal, Nabil et al.  
US 20040093018 A1 Johnson, Gary M. et al.  
US 20050059865 A1 Kahle, Henry et al.  
US 20030050604 A1 Lui, Chun Kee et al.  
US 20010049499 A1 Lui, Chun Kee et al.  
US 5556387 A Mollenauer; Kenneth H. et al.  
US 4978341 A Niederhauser; Werner  
US 6117086 A Shulze; John E.  
US 20040106942 A1 Taylor, Scott et al.  
US 5441486 A Yoon; InBae  
US 5389080 A Yoon; InBae  
US 5429609 A Yoon; InBae  
US 5989233 A Yoon; InBae  
US 5989232 A Yoon; InBae  
US 5788676 A Yoon; InBae

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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